IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
EASTERN DIVISION

Case No. 4:25-CV-00076-M-RJ

VAPOR TECHNOLOGY ASSOCIATION, et al.,

Plaintiffs,

v.

MCKINLEY WOOTEN, JR., *in his official capacity as* NORTH CAROLINA SECRETARY OF REVENUE, et al.,

Defendants.

ORDER

Plaintiffs—a coalition of manufacturers, retailers, and users of electronic nicotine delivery systems ("ENDS" or "e-cigarettes")—brought this action against three North Carolina officials for declaratory and injunctive relief. They seek to enjoin enforcement of North Carolina Session Law 2024-31 ("S.L. 2024-31), a recently enacted state statute that partially conditions the sale of e-cigarettes on compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA"). Pending before the court are Plaintiffs' Motions for Temporary Restraining Order [DE 30] and Preliminary Injunction [DE 23]. Plaintiffs contend that S.L. 2024-31 violates the Supremacy Clause of the United States Constitution because the FDCA impliedly preempts any state law that attempts to enforce its provisions. For the following reasons, the motions are denied.

I. Background

Enacted in 1938, the FDCA has long required the approval of the Food and Drug Administration ("FDA") before a new drug can be introduced into the market. Pub. L. No. 75-717, 52 Stat. 1040 (1938). In 2009, the FDCA was amended by the Family Smoking Prevention

and Tobacco Control Act ("TCA") to extend this supervisory authority over "new tobacco products." Pub. L. 111-31, 123 Stat. 1776 (2009) (codified as amended at 21 U.S.C. § 387j). "When modern e-cigarettes made their American debut, the FDA did not treat them as 'new tobacco products' for purposes of the TCA." *FDA v. R. J. Reynolds Vapor Co.*, 606 U.S. __, __ (2025) (slip op., at 1). As a result, they could be introduced into the market unhindered by FDA oversight. In 2016, the FDA changed course and declared that e-cigarettes were, in fact, subject to the provisions of the TCA. 81 Fed. Reg. 29028–29044 (2016). Congress has since approved that interpretation and clarified that the term "tobacco products" encompasses products containing nicotine from "any source"—including, as relevant here, synthetic nicotine. Pub. L. No. 117-103, 136 Stat. 789 (2022) (codified at 21 U.S.C. § 321(rr)(1)).

For a company to receive FDA approval for a "new tobacco product," it must submit a premarket tobacco product application ("PMTA"). 21 C.F.R. § 1114.1(a). If the PMTA demonstrates that the product meets all applicable requirements, the FDA will issue a marketing granted order. § 1114.5. "A new tobacco product may not be introduced or delivered for introduction into interstate commerce . . . until the FDA has issued" a marketing granted order. *Id.* To date, thirty-four e-cigarette products have received the necessary market approval, and the parties agree that none of the approved products are those manufactured or sold by the corporate Plaintiffs. *See* https://www.accessdata.fda.gov/scripts/searchtobacco/ (last visited June 25, 2025); [DE 24] at 6; [DE 27] at 6.

As the Supreme Court recently observed, "[g]iven the size of the e-cigarette market, pulling products from the shelves while manufacturers sought 'premarket' authorization to sell them would have been disruptive." *R. J. Reynolds Vapor Co.*, 606 U.S. __ (slip op., at 2). "To mitigate the disruption, the FDA announced that it would defer enforcement of the TCA against e-cigarette

manufacturers and retailers while the manufactures sought FDA approval." *Id.* The most recent guidance advised that the FDA would defer enforcement of the TCA against unauthorized ENDS until September 2020, provided that the products were on the market by August 8, 2016, and the relevant PMTA was submitted by September 9, 2020.[1] With these deadlines now expired, the FDA exercises its enforcement power on a "case-by-case" basis. *Id.* at 10.

With the passage of S.L. 2024-31, North Carolina created a regulatory framework by which the North Carolina Department of Revenue certifies vapor products—including e-cigarettes—as eligible for sale in North Carolina. N.C. Gen. Stat. § 14-313(g); *see also* § 14-313(a)(5) (defining vapor products as including e-cigarettes). To be eligible for sale, an e-cigarette's manufacturer[2] must, on an annual basis, certify to the Secretary that the product: (1) received a marketing granted order from the FDA; (2) was on the market as of August 8, 2016, and an associated PMTA was submitted to the FDA on or before September 9, 2020;[3] or (3) the product is exempt from both previous subsections because its existence reflects only a change to its name, brand style, or packaging. § 143B-245.11(a)(1)–(3). The Act directs the Secretary of Revenue, beginning May 1, 2025, to maintain a publicly available directory listing all manufacturers and individual e-cigarette products for which certifications have been approved. § 143B-245.12(a). Expressly excluded from this directory are any product for which the Secretary determines that the

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[1] U.S. Food & Drug Admin., Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) (Apr. 2020), at 31–32.

[2] The Act uses the phrase "manufacturer" but specifies that its provisions apply whether the manufacturer sells vapor products directly to the consumer or does so through a distributor, retailer, or similar intermediary. *See* § 143B-245.11(a).

[3] Notably, this exception applies only to products "containing nicotine derived from tobacco." N.C. Gen. Stat. § 14-313(a)(3c). This is relevant as Plaintiffs' products largely contain synthetic nicotine, so regardless of whether an otherwise timely PMTA was submitted to the FDA, the products are ineligible for certification under North Carolina law unless they have received FDA market approval. Compl. [DE 1] at ¶ 12.

manufacturer: (1) failed to provide a complete and accurate certification; (2) submitted a certification that does not comply with the statutory requirements; (3) failed to include with its certification the required payment; (4) previously "sold products in North Carolina required to be certified under this Part during a period when either the manufacturer or the product had not been certified and listed on the director"; or (5) provided information in its certification that was false or contained a material misrepresentation or omission. § 143B-245.12(b). Manufacturers and retailers who sell e-cigarettes in North Carolina that are not listed on the directory are subject to fines and other civil penalties. § 14-313(h).

On May 1, 2025, the North Carolina Department of Revenue published its directory, triggering a 60-day grace period in which manufacturers and retailers are required to sell or otherwise dispose of unauthorized inventory.[4] *See* § 143B-245.13(a). This grace period will end on June 29, 2025.[5]

One day before the directory was published, Plaintiffs filed this action, arguing S.L. 2024-31 violates the Supremacy Clause of Article IV and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution. [DE 1] at 21, 23. On May 16, 2025, Plaintiffs moved for a preliminary injunction. [DE 23]. Almost a month later, on June 13, 2025, Plaintiffs moved for a temporary restraining order. [DE 30]. Both motions are fully briefed, and the matter is ripe for review.

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[4] Vapor Certification Directory, https://www.ncdor.gov/taxes-forms/other-taxes-and-fees/vapor-product-and-consumable-product-certification-and-directory/vapor-certification-directory (last visited June 26, 2025).

[5] NCDOR, Frequently Asked Questions Regarding the North Carolina Vapor Products and Consumable Products Certification and Directory, at 1 (Feb. 19, 2025).

II. Legal Standards

"The standards for granting a TRO and granting a preliminary injunction are the same." *ClearOne Advantage, LLC v. Kersen*, 710 F. Supp. 3d 425, 431 (D. Md. 2024). "Under this standard, a party seeking a TRO must demonstrate that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest" *Id.* (citing *Winter v. Nat. Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008)). "[A] district court is entitled to deny preliminary injunctive relief on the failure of any single *Winter* factor, without fully evaluating the remaining factors." *Vitkus v. Blinken*, 79 F.4th 352, 361 (4th Cir. 2023).

III. Discussion

A. Standing

Defendants argue that Plaintiffs lack standing to bring suit, which implicates the court's subject matter jurisdiction. Federal "courts must always assure themselves of subject matter jurisdiction before reaching the merits," so the court resolves this question before proceeding to Plaintiffs' request for injunctive relief. *Virginia Dep't of Corr. v. Jordan*, 921 F.3d 180, 187 (4th Cir. 2019).

Article III of the United States Constitution "confines the federal judicial power to the resolution of 'Cases' and 'Controversies.'" *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021); *see* U.S. Const. art. III, § 2, cl. 2. For a lawsuit to constitute a case under Article III, a plaintiff "must have a 'personal stake' in the case—in other words, standing." *Id.* (quoting *Raines v. Byrd*, 521 U.S. 811, 820 (1997)). The "irreducible constitutional minimum" of standing requires a showing of three elements. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). The plaintiff must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged

conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (citing *Lujan*, 504 U.S. at 560–61). An injury in fact requires the invasion of a "legally protected interest" that is concrete, particularized, and actual or imminent. *Id.* at 339 (quoting *Lujan*, 504 U.S. at 560).

Defendants' argument is predicated on the phrase "legally protected interest" found in *Lujan*. They argue that because Plaintiffs' e-cigarettes cannot lawfully be introduced into interstate commerce under the FDCA, they do not have a "legally protected interest" in selling those products. [DE 27] at 10. As has been observed by other courts, this reading of *Lujan* "distorts the Supreme Court's standing jurisprudence." *Iowans for Alternatives to Smoking & Tobacco, Inc. v. Iowa Dep't of Revenue*, No. 4:24-cv-00448, -- F. Supp. 3d --, at *6 (D. Iowa May 2, 2025). The standing doctrine does not presume upon the merits a party's claim. *White Tail Park, Inc. v. Stroube*, 413 F.3d 451, 460 (4th Cir. 2005) (citing *Warth v. Seldin*, 422 U.S. 490, 500 (1975)). The Supreme Court has previously rejected a "legal right" theory of standing, and the court in *Lujan* did not resurrect it. *See Ass'n of Data Processing Serv. Org., Inc. v. Camp*, 397 U.S. 150, 153 (1970). Instead, in making this articulation, the court approvingly cited to three of its prior cases, each of which spoke about whether an interest was judicially "cognizable." *Lujan*, 504 U.S. at 560 (citing *Warth*, 422 U.S. at 508 ("Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of the statute."); *Allen v. Wright*, 468 U.S. 737, 755–56 (1984) (finding that a stigmatic injury was not "judicially cognizable"); *Sierra Club v. Morton*, 405 U.S. 727, 734–35 (1972) (finding that the "injury in fact test requires more than an injury to a cognizable interest")). Properly understood, then, *Lujan* and its progeny require only that the interest at stake be a legally cognizable one or, in other words, "one

recognized at common law, by statute, or the Constitution[.]" *Sipe v. Equifax Info. Serv., LLC*, No. 3:16-6103, 2017 WL 253157, at *4 (S.D.W.V. Jan. 20, 2017).

Here, the court is satisfied that Plaintiffs have standing. Should S.L. 2024-31 be enforced, Plaintiffs will suffer substantial economic harm, including the loss of sales revenue and the incursion of civil fines imposed by the North Carolina Department of Revenue. *See* Salaymeh Decl. [DE 24-2] at ¶ 16, 18 (advising that only 1.3% of Plaintiff AMV Holdings' revenue from ENDS sales comes from products listed on the directory and that the loss of this revenue would force the company to close 80% of its brick-and-mortar stores); Shupe Decl. [DE 24-12] at ¶ 9, 11–12 (advising that the comparable percentage for Plaintiff Bright Leaf Vendors is 3-4%). These types of economic injuries are the quintessential example of concrete harm recognized by the standing doctrine. *United State v. Texas*, 599 U.S. 670, 676 (2023) ("Monetary costs are of course an injury."). Further, these injuries are imminent and directly traceable to enforcement of S.L. 2024-31. Beginning this Sunday, the sale of all e-cigarettes in North Carolina not on the state directory will be prohibited and punishable by law. *See* § 143B-245.13(a). Should enforcement be enjoined, Plaintiffs would continue to sell their products, thus avoiding the loss of revenue described above. In sum, Plaintiffs have met all three prongs of standing.[6] *See Lujan*, 504 U.S. at 560–61.

[6] As "the presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement," the court need not evaluate whether the consumer Plaintiff, Reagan Murphy, has standing to sue in her own right. *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 52 n.2 (2006).

B. Preliminary Injunction

On the merits, Plaintiffs argue that S.L. 2024-31 violates the Supremacy Clause because it is impliedly preempted by the FDCA.[7] Specifically, they contend that because the state statute references the FDCA's premarket authorization requirements for e-cigarettes, it improperly seeks to "deputize the North Carolina Department of Revenue to enforce those provisions." [DE 24] at 20. The court disagrees.

The Supremacy Clause of the United States Constitution provides that "the Laws of the United States" are "the supreme Law of the Land." U.S. Const. art. VI. "Practically speaking, this means that federal law preempts—or bars—claims under state law that either interfere with or are contrary to federal laws." *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 336 (4th Cir. 2023). When confronted with a preemption claim, courts start "with the basic assumption that Congress did not intend to displace state law." *S. Blasting Serv., Inc. v. Wilkes Cnty. NC*, 288 F.3d 584, 589 (4th Cir. 2002) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). This presumption is strongest when "Congress legislates in a field which the States have traditionally occupied." *Id.* at 590 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Indeed, "the historical police powers of the States" are not assumed to be superseded by federal law "unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 485.

Preemption can be express or implied. *See Silkwood v. Kerr-McGee Gorp.*, 464 U.S. 238, 248 (1984). Where, as here, an implied preemption claim is made, the court must consider whether "the state law stands as an obstacle to the accomplishment of the full purposes and objectives of

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[7] In their complaint, Plaintiffs also allege that S.L. 2024-31 violates the Equal Protection Clause of the Fourteenth Amendment. [DE 1] at 23. They do not flesh out this argument in the present briefing, however, so the court finds that they have not "establish[ed] that [they] are likely to succeed on the merits" of an Equal Protection claim. *See Winter*, 555 U.S. at 20.

Congress." *Id.* If the state law would "prevent or frustrate" this federal objective, it is "nullified" by the Supremacy Clause. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000).

Here, Congress' intent (as relevant to Plaintiffs' claim) is evidenced by several provisions of the FDCA that address the circumstances in which a state is permitted to regulate tobacco products. First, the FDCA contains an enforcement provision that states that all proceedings to enforce or restrain violations of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has recognized this language as "clear evidence that Congress intended" the FDCA to "be enforced exclusively by the Federal Government." *Buckman Co. Plaintiff's Legal Comm.*, 531 U.S. 341, 352 (2001). Second, in a Preservation Clause, Congress clarified as to the Tobacco Products subchapter that

> except as provided in paragraph (2)(A), nothing in this subchapter . . . shall be construed to limit the authority of a . . . State or political subdivision of a State . . . to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements under this subchapter . . . relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products.

21 U.S.C. § 387p(a)(1). This explicit acknowledgement of authority is limited by a Preemption Clause, which prohibits states from promulgating requirements "relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." § 387p(a)(2)(A). Finally, the text reiterates that the Preemption Clause "does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, the advertising and promotion of, or use of, tobacco products[.]" § 387p(a)(2)(B) ("Savings Clause").

Plaintiffs argue that because S.L. 2024-31 references the FDCA's premarket requirements for e-cigarettes, it improperly seeks to enforce the provisions of the FDCA, in violation of § 337(a).

For two reasons, the court disagrees. First, this argument would render the Preservation and Savings Clauses a nullity. Plaintiffs note that the existence of such clauses "does not bar the ordinary working of conflict pre-emption principles." *See Geier*, 529 U.S. at 869. This is, of course, true, but it does not change the fact that by the FTCA's own terms, state regulation of tobacco sales neither frustrates nor prevents the FTCA's objectives. *See id.* at 873. Indeed, while Section 337(a) specifically requires that only the United States may initiate proceedings to enforce provisions of the FTCA, the Preservation Clause explicitly does not "limit the authority" of a State to enact and enforce laws with respect to the sale of tobacco products. § 387p(a)(1). Because Plaintiffs' reading of the statute would require this court to ignore that directive, the court declines to adopt it.

Second, contrary to Plaintiffs' assertion, S.L. 2024-31 is not an attempt to "deputize the North Carolina Department of Revenue" to enforce other provisions of the FTCA. [DE 24] at 20. In other words, it is not a premarket review regulatory scheme disguised as a sales prohibition. Critically, noncompliance with the FTCA is not itself an actionable basis for the Secretary of Revenue to initiate proceedings under S.L. 2024-31. Instead, a manufacturer or retailer only runs afoul of state law upon the "retail sale" of a vapor product "not included in the directory." § 14-313(h)(1). Some products on the directory are compliant with the FTCA. Others are not. *See* 143B-245.11(a)(2) (permitting products for which a timely, but unapproved, PMTA has been submitted). Ultimately, because North Carolina tied violations of state law with the retail sale of tobacco products, it lawfully exercised its preserved authority. *See* § 387p(a)(1).

Accordingly, at this juncture, the court finds that Plaintiffs are highly unlikely to succeed on the merits of their preemption claim and, thus, that preliminary relief is inappropriate. *See Winter*, 555 U.S. at 20.

IV. Conclusion

For foregoing reasons, Plaintiffs' Motion for Temporary Restraining Order [DE 30] and Motion for Preliminary Injunction [DE 23] are DENIED.

SO ORDERED this 27th day of June, 2025.

Richard E Myers II

RICHARD E. MYERS II
CHIEF UNITED STATES DISTRICT JUDGE